

DETAILED ACTION

Applicants canceled originally submitted claims 1-12 and submitted new claims 14-24 for examination on merit in their amendments submitted on 12/4/09.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Lydia McNally and Mr. Markus Gruber on 3/1/10.

The application has been amended as follows:

Please cancel **claim 13**.

Claim 14 (currently amended) Please replace the term '**branched**' on line 3 with the term '**star**' in its place.

Please replace the claim 16 with the following.

Claim 16 (currently amended) Microparticles according to claim 14 wherein the polymer matrix comprises a linear polylactide-co-glycolide polymer and a star polylactide-co-glycolide polymer having a weight average molecular weight of about 50,000 Da.

Claim 17 (currently amended) Please replace the term '**branched**' on line 1 with the term '**star**' in its place.

Reasons for allowance

The following is an examiner's statement of reasons for allowance:

1. The closest prior art, Bodmer, Journal of Controlled Release, 1992, 21, 129-138 teaches the use of branched poly(DL-lactide-co-glycolide-D-glucose) for the preparation of microspheres and linear poly(DL-lactide-co-glycolide) for the implants. However, the prior art does not teach or suggest, alone or in combination, the instantly claimed combination of linear and branched (star) poly(DL-lactide-co-glycolide-D-glucose) polymer for the preparation of microparticles comprising cyclo[{4-(NH₂-C₂H₄-NH-CO-O-)Pro}-Phg-DTrp-Lys-Tyr(4-Bzl)-Phe].
2. The closest prior art, Pistel, Journal of Controlled Release, 1999, 59, 309-325 teaches the use of branched poly(DL-lactide-co-glycolide-D-glucose) with a central core of poly(ethyleneoxide) (PEO) and linear poly(DL-lactide-co-glycolide) and investigated their potential for their sustained drug (EPO) delivery systems. The results indicated that amount of EPO aggregates in star shaped polymers was comparable to linear polymers. An initial burst of EPO was observed in star polymer matrix and a continuous release of protein from the star shaped polymers could not be achieved (conclusions on page 324, column 1). However, the prior art does not teach or suggest, alone or in combination, the instantly claimed combination of linear and branched (star) poly(DL-lactide-co-glycolide-D-glucose) polymer for the preparation

of microparticles comprising cyclo[{4-(NH₂-C₂H₄-NH-CO-O-)Pro}-Phg-DTrp-Lys-Tyr(4-Bzl)-Phe].

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SATYANARAYANA R. GUDIBANDE/
Examiner, Art Unit 1654

/Andrew D Kosat/
Primary Examiner, Art Unit 1654